Claim Amendments

New claim 31 is supported in the specification on page 91, line 10. New claims 32-35 are supported in the specification in Figure 5. No new matter is added to the disclosure as a result of entering these amendments.

The amendments to claims 20, 21, and 28 are supported *inter alia* by the claims as originally presented. They are made voluntarily, and do not narrow the scope of the claimed subject matter.

Priority filing and Patent Term

By way of this amendment, applicants have dropped priority claim under 35 USC § 120 to all prior applications except 08/979,742.

Applicants request that the term of the patent issued from this application be calculated using the filing date of the 08/979,742 application (November 26, 1997) as the first priority date.

Objections to Priority Claim and Declaration

The priority claim under 35 USC § 120 has been objected to in the Office Action dated April 25, 2001, as not indicating that one of the previous applications has now been abandoned. By way of this amendment, the objection has been rectified.

The Office Action also indicates that the Oath or Declaration is defective for not reciting all the prior applications to which this application claims priority. Applicants understand that Declarations under 37 CFR § 1.63 no longer need to refer to the priority applications. Form PTO/SB/01 (the standard Declaration form provided by the Office) is consistent with this practice. Clarification is requested.

Rejections under 35 USC § 112 ¶ 1

Claims 20, 23, and 26 stand rejected under § 112 ¶ 1 for not describing the invention in such a way as to convey that the inventors had possession of the claimed invention. Claims 20, 23, and 26 also stand rejected under 112 ¶ 1 as not being enabled for sequences other than SEQ. ID NO:2 that have telomerase catalytic activity when associated with telomerase RNA. Both objections refer to the indication that the protein has at least 90% sequence identity.

Applicants respectfully disagree. One skilled in the art would recognize that applicants had possession of the invention as required by the standard required by *Regents of University of California v.Eli Lilly & Co..,* 43 USPQ2d 1398 (Fed. Cir. 1997). The species disclosed (SEQ. ID NO:2) is representative of the genus, because all members have at least 90% structural identity with the reference compound. The claim further requires that any member of the genus share the feature of having telomerase catalytic activity when associated with a telomerase RNA.

The Examiner is respectfully referred to the Written Description Training Examples issued by the Office. Example 9 indicates that claims reciting stringent hybridization conditions and functional activity meet the written description requirements. Example 14 indicates that claims reciting a degree of sequence homology and functional activity meet the written description requirements.

With regards to the enablement requirement, applicants point out that the specification provides a number of assays for determining telomerase activity, as recited in the claim. See, for example, page 63, line 21 to page 67, line 27. One skilled in the art may readily make variants of SEQ. ID NO:2 by introducing mutations by standard techniques, and then testing the mutants for telomerase activity according to the assay. Similarly, one having possession of a model protein may determine whether it falls within the scope of the claim by comparing the sequence to determine if it is 90% identical, and then conducting a telomerase assay to determine whether it has the required functional activity. Accordingly, the scope of the claimed invention is enabled by the specification.

Enclosed with this application is an Information Disclosure Statement that includes U.S. Patents 6,284,477; 6,287,839; 6,291,220; 6,297;356; and 6,297,367, which have issued in the last 2 months. These patents all claim polypeptides or polynucleotides on the basis of 80% or 90% homology to a representative sequence, in combination with functional activity. Patent No. 6,297,356 is of particular interest, because it claims another protein which is believed to be involved in telomere biology.

Withdrawal of this rejections is respectfully requested.

Claims 23-25 stand rejected under 35 USC § 112 ¶ 1 as being enabled for an isolated cell, but not for cells in vivo. Claim 28 stands rejected under § 112 ¶ 1 as being non-enabled by the specification because it accommodates a cell that is within a transgenic mouse.

Applicants respectfully disagree. If the making of a claimed compound is enabled by the specification, then the compound is patentable under § 112 ¶ 1, regardless of the context in which it may be found. Claims to the isolated, purified or recombinant polynucleotide (claims 20-22) refer to and are enabled for the polynucleotide in any context, including in living cells. Similarly, claims to cells containing the polynucleotide (claims 23-25) refer to and are enabled for cells in any context. The Office Action further contends that claims 23-25 fall "in the realm of gene therapy", which is asserted to be an unpredictable field. Applicants disagree that gene therapy is unpredictable in all contexts, especially those illustrated in the specification.

Secondly, the application illustrates vectors for the expression of recombinant mTERT in eukaryotic cells (such as may be used in vitro or in vivo), and the construction of knockout mice. See Examples 3 and 4 (pages 103 to 116). It is well established in the law that a specification can adequately describe the manner and process of making an embodiment of an invention, whether or not it has actually been conducted. Use of prophetic examples does not make a patent non-enabling. The burden is on the person challenging the patent to show that the prophetic examples together with other parts of the specification are not enabling. *Atlas Powder Co. v. E.I. du Pont de Nemours & Co.,* 224 USPQ 409 (Fed. Cir. 1984).

By way of further illustration, attached to this Response is a Declaration under 37 CFR § 1.132 by Choy-Pik Chiu, Ph.D., Senior Director at Geron Corporation. Dr. Chiu

explains that mTERT expression vectors have been used as part of a project to study the immune response to telomerase in mice. She also indicates that mice are being generated that are heterozygous and homozygous for inactivation of the mTERT gene. Other scientists have produced mTERT transgenic mice and mTERT knockout mice, according to the description in this application.

Withdrawal of these objections is respectfully requested.

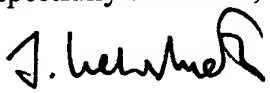
Conclusion

Applicants respectfully request that all outstanding rejections be reconsidered and withdrawn in light of the remarks made herein. These papers are believed to place the application in condition for allowance, and an early Notice of Allowance is requested.

In the event that the Examiner determines that there are other matters to be addressed, he is invited to contact applicant's representative at the telephone number indicated below.

Should the Patent Office determine that a further extension of time or any other relief is required for further consideration of this application, applicant hereby petitions for such relief. The Assistant Commissioner is hereby authorized to charge the cost of such petitions and other fees due in connection with the filing of this Amendment to the Deposit Account.

Respectfully submitted,



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VERSION WITH MARKINGS TO SHOW CHANGES MADE

20. (Amended) An isolated, purified or recombinant polynucleotide encoding a ~~mouse~~ telomerase reverse transcriptase ~~(mTERT)~~ protein, wherein said protein:

(i) has at least 90% sequence identity to SEQ ID NO:2; and,

(ii) has telomerase catalytic activity when associated with telomerase RNA.

21. (Amended) The polynucleotide of claim 20, wherein the encoded ~~mTERT~~ telomerase reverse transcriptase protein has an amino acid sequence of SEQ ID NO:2.

28. A mouse cell in which an endogenous ~~mTERT~~ telomerase reverse transcriptase gene in the cell has been mutated by recombinant means, ~~wherein said cell is deficient in telomerase catalytic activity,~~ or progeny of said cell.

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